

PSORIASIN DEEP MOISTURIZING 4 OZ.- coal tar ointment
Denison Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Psoriasis Deep Moisturizing Ointment (4 oz.)

Active ingredient

Coal Tar 2% (from Coal Tar Topical Solution, USP 20%)

Purpose

Psoriasis/Seborrheic Dermatitis Treatment

Uses

For the relief of symptoms associated with psoriasis and/or seborrheic dermatitis including itching, scaling, flaking, redness and irritation of the skin. Helps prevent recurrence.

Warnings

For external use only.

Ask a doctor before use

- for prolonged periods
- if condition covers a large area of the body
- around the rectum or in the genital area or groin
- with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs.

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- condition worsens
- condition does not improve after regular use of this product as directed.

Use caution in exposing skin to sunlight after applying this product, as it may increase your tendency to sunburn for up to 24 hours after application.

Warning: This product contains chemicals known to the State of California to cause cancer.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- Read all package directions and warnings before use.
- Use only as directed.
- Apply (gently massage in) a small amount of Psoriasis to affected areas.
- Apply one to four times daily or as directed by a doctor.
- Apply to thoroughly dry skin.

- Not recommended for scalp or hairline areas.
- The active ingredient, coal tar, in Psoriasin Ointment may affect very light hair color; test first on a few strands of hair before broader application to areas where light colored hair is present.
- Wash affected areas at least daily with mild soap and warm water and dry thoroughly.
- Intended for use by normally healthy adults only.
- Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor.

Other information

You may report serious side effects to the phone number provided under Questions? below.

Inactive ingredients

Ethanol, petrolatum, polysorbate 80.

Questions?

1-800-792-2582

Psoriasin Ointment Insert

PSORIASIN DEEP MOISTURIZING OINTMENT

DERMATOLOGIST RECOMMENDED

- Stops Psoriasis itching, scaling, redness
- Can complement topical steroids
- Visible results in just days
- Helps prevent recurrence

Psoriasin Deep Moisturizing Ointment treats psoriasis symptoms where they start, to help stop the itching, flaking, redness and related discomforts associated with psoriasis. Formulated in a soothing ointment base, it penetrates the skin while the rich moisturizing ingredients help create a barrier to lock in moisture for hours - so it's great for overnight use. Use **Psoriasin Deep Moisturizing Ointment** to relieve symptoms of psoriasis and to help restore your skin to a more natural looking appearance.

How Coal Tar Works

The coal tar in **Psoriasin Deep Moisturizing Ointment** slows down the excessive skin cell production that is the root cause of psoriasis symptoms. No other FDA compliant non-prescription drug ingredient works this way. Slowing excessive skin cell production means it can help reduce the itching, scaling and redness of psoriasis. With regular use as directed, **Psoriasin Deep Moisturizing Ointment** can even help prevent recurrence of psoriasis symptoms. And coal tar can be used to complement topical steroid therapies.

The Role of Topical Steroids

Topical steroids - similar to the natural corticosteroid hormones produced by the adrenal glands - are a frequently used psoriasis symptom treatment. Topical steroids are used as anti-inflammatory agents to reduce the swelling and redness of lesions. Although topical steroids can produce rapid symptom relief, continuous use of them may cause potential side effects such as skin thinning.

Topical Therapy Choices for Psoriasis Symptom Control

Due to the well documented side effects of topical steroids, some experts recommend using intermittent therapy (also called weekend or pulse therapy). This type of treatment involves applying a topical

steroid for three consecutive days each week followed by four days of a coal tar medication like **Psoriasis Deep Moisturizing Ointment**. Ask your doctor if this approach might be right for you.

PSORIASIS SELF-CARE TIPS

In addition to psoriasis treatments recommended by a doctor, you can help reduce psoriasis symptoms by using self-care approaches, including:

Keep Skin Moisturized

Using a moisturizer is an important part of self-care for psoriasis. Dry skin makes irritation and itching caused by psoriasis worse than it needs to be. A vicious cycle can result: dry skin can cause itching and scratching, leading to new psoriasis patches developing on the irritated skin. Dermatologists recommend ointments and heavy creams to lock water into the skin.

Bathe with Care

Too many baths and showers can dry your skin. Here are a few suggestions:

- Don't bathe or shower with hot water, which can irritate. Use lukewarm water instead.
- Don't dry off by rubbing with a towel. Pat yourself somewhat dry and then apply cream.
- Plain water can dry your skin. Adding salts, oil or finely ground oatmeal to bath water can help to soothe your skin.
- Take fewer showers and baths. They can strip your skin of natural oils. Bathe every other day or every third day, especially during the winter months.

Reduce Stress

Stress can cause psoriasis to flare for the first time or aggravate existing psoriasis. Relaxation and stress reduction may help prevent stress from making your psoriasis worse.

- Engage in relaxation techniques, such as yoga, meditation, or massage
- Exercise regularly
- Get enough sleep

Be Smart About Sunlight

The ultraviolet rays in sunlight slow the growth of skin cells, so getting moderate doses of sun is good. But make it brief and use sunscreen, because sunburn can trigger psoriasis flare-ups. Some medications can make your skin more sensitive to ultraviolet rays, so talk to your doctor first.

Stick to the Plan

Applying creams or ointments day after day can be inconvenient. But compliance is the key for topical therapies. Once you have a topical treatment regimen that's working for you, making it part of your daily routine can improve results. Also, topical therapies help you avoid the potential side effects of systemic treatments for psoriasis.

The active ingredient in **Psoriasis Deep Moisturizing Ointment** has been recognized to be safe and effective by an FDA Expert Advisory Panel when used as directed.

USE THE FAMILY OF PSORIASIN PRODUCTS TO BUILD YOUR PSORIASIS TREATMENT REGIMEN:

- **PSORIASIN PROBLEM SKIN FORMULA CREAM** Combines a low dose of coal tar with botanicals & Vitamin D3 in a soothing cream that won't irritate sensitive skin.
- **PSORIASIN DEEP MOISTURIZING OINTMENT** Delivers coal tar in a base that locks in moisture for hours to help restore your skin's appearance.
- **PSORIASIN DAYTIME RELIEF VANISHING GEL** Is a quick-drying, low-odor coal tar therapy

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Psoriasis[®]

DEEP MOISTURIZING OINTMENT

Drug Facts

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Drug Facts (continued)

Warnings (continued)

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Questions? 1-800-792-2582

CONTAINS NO GLUTEN INGREDIENTS www.PSORIASIN.com

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DERMATOLOGIST RECOMMENDED

STOPS PSORIASIS
ITCHING + SCALING + REDNESS

Can Complement Topical Steroids
Visible Results in Just Days
Helps Prevent Recurrence

DERMATOLOGIST RECOMMENDED

NET WT 4 OZ (113 g)
TOPICAL OINTMENT

DERMATOLOGIST RECOMMENDED

DEEP MOISTURIZING OINTMENT

DEEP MOISTURIZING OINTMENT

DERMATOLOGIST RECOMMENDED

PSORIASIS[®]

PSORIASIS[®]

PSORIASIS[®]

LOT: EXP:

Prod. No.: 78004

ALVA-AMCO Pharmaceutical Cos., Inc.
Niles, IL 60714, U.S.A.
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Reg. U.S. Patent and Trademark Office

Coal tar has been recognized as safe and effective by the FDA, when used as directed.

KEEP TIGHTLY CLOSED WHEN NOT IN USE. STORE AWAY FROM EXCESSIVE HEAT AND COLD.

*Based on independent syndicated market research data.



PSORIASIN DEEP MOISTURIZING 4 OZ.

coal tar ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0295-7800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-7800-13	1 in 1 CARTON	01/21/2019	
1		113 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/21/2019	

Labeler - Denison Pharmaceuticals LLC (001207208)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals LLC		001207208	manufacture(0295-7800)

Revised: 1/2019

Denison Pharmaceuticals LLC